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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,904

09/07/2004

Yehoshua Yeshurun

1975/43

7073

44696

7590

02/20/2009

DR. MARK M. FRIEDMAN

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/506,904	<b>Applicant(s)</b> YESHURUN ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-13,15-18,20-25 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-13,15-18,20-25 and 53-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Response to Amendment/Acknowledgements***

The Examiner acknowledges the reply filed 11/26/2008 in which claims 1, 4, 8-9, 13, 16-17, 20-21, and 53-54 were amended and claims 7 and 19 were cancelled.

Although some of claimed subject matter from claims 7 and 19 was incorporated into the independent claims, **not all of the previously claimed** elements present within claims 7 and 19 were incorporated (flow conduit structure through substrate), **therefore the amendments to the claims broaden and change the scope of the claims** that were last filed 02/09/2007 and the following office action is made FINAL.

Currently claims 1-6, 8-13, 15-18, 20-25 and 53-56 are pending for examination in this application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Palmer (USPN6,537,242). Palmer discloses a device and method for enhancing skin penetration for intradermal administration of a substance.

Regarding claims 1 and 10-11, Palmer discloses a microneedle device (Figures 3-6) for transporting fluid across a biological barrier (skin, 50), the device comprising: (a) a fluid transport configuration including: (i) a substrate (14) defining a substantially planar surface, and (ii) a plurality of microneedles (43) projecting from said substantially planar surface; and (iii) a conduit (axial lumen through 43) extending through at least part of the microneedle, (b) an abutment member (16, 64) having at least one abutment surface with adhesive (59) for abutting the biological barrier (50), said abutment member configured to anchor a region of the biological barrier so as to oppose movement of the biological barrier and provide a stretching force parallel to a surface of the biological barrier (Figure 5); and (c) a displacement mechanism (12) mechanically linking between said abutment member (16, 64) and said fluid transport configuration, said displacement mechanism (44) defining a path of movement of said fluid transport configuration relative to said abutment surface (perpendicular, see Figures 5 and 9 ), at least part of said path of movement being such that said microneedles (43) move in contact with the biological barrier in a direction having a non-zero component parallel to the surface of the biological barrier (50) (see Figures 1-10, cols 1-2)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3-4, 7-8, 13, 15-17, 19-20, 22-24, 53-54 and 56 are rejected under 35 U.S.C 103(a) as being unpatentable over Palmer (USPN6,537,242) in view of Olson (USPN 6,749,792). Palmer meets the claim limitations as described above except for the specific needle design orientation.

However, Olson teaches a micro-needle and method of manufacture.

Regarding claims 2, 3-4, 7-8, 13, 15-17, 19-20, 22-24, 53-54 and 56, Olson teaches a microneedle system (80) that each of said microneedles (75) has a base-to-tip vector defined as a vector from a centroid of a base area of said microneedle to a centroid of a penetrating tip (60) of said microneedle, said microneedles being asymmetrical such that said base-to-tip vector is non-perpendicular to said substantially planar surface (near 50), a direction parallel to a projection of said base-to-tip vector on to said substantially planar surface being taken to define a penetration direction, and wherein at least part of said path of movement has a non- zero component along said penetration direction wherein the microneedles are formed with a upright surface (75) nearly perpendicular to the planar surface and with a conduit (55) extending through at

least part of said microneedle which comprises an inclined surface (top surface of needle near 63) (Figures 2A-3B).

At the time of the invention, it would have been obvious to use the microneedles of Olson with the system of Palmer in order to optimize the needle structure for maximal drug delivery or fluid removal. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Olson (col 2).

### ***Claim Rejections - 35 USC § 103***

Claims 12 and 25 are rejected under 35 U.S.C 103(a) as being unpatentable over Palmer (or Palmer in view of Olson) in view of Avrahami et al. (US2002/0038101). Palmer meets the claim limitations as described above except for the vibration generator.

However, Avrahami et al. teaches an electronic card for transdermal delivery and analyte extraction.

Regarding claims 12 and 25, Avrahami et al. teaches a microneedle device (40) comprising a vibration generator ([0128]) associated with said fluid transport configuration and deployed so as to generate vibration of said fluid transport configuration so as to enhance penetration of said microneedles into the biological barrier (Figures 1A).

At the time of the invention, it would have been obvious to include the vibration system of Avrahami et al. with the system of Palmer in order to further increase the microneedle insertion and reduce pain associated with the needle abrasion. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Avrahami et al. (cols 1-2).

***Claim Rejections - 35 USC § 103***

Claims 9 and 21 are rejected under 35 U.S.C 103(a) as being unpatentable over Palmer in view of Olson in further view of Palasis et al. (USPN6,319,230). The modified Palmer meets the claim limitations as described above except for the high pressure needle jet mechanism.

However, Palasis et al. teaches a lateral needle injection apparatus and method.

Regarding claims 9 and 21, Palasis et al. teaches a microneedle system (10) in which a high pressure system (20) is used to provide delivery fluid into a biological substrate (Figures 1A-1B).

At the time of the invention, it would have been obvious to add the high pressure generation system of Palasis et al. to the modified system of Palmer in order to further increase the depth of drug delivery. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Palasis et al. (cols 1-2).

***Claim Rejections - 35 USC § 103***

Claims 5-6, 18 and 55 are rejected under 35 U.S.C 103(a) as being unpatentable over Palmer (or Palmer in view of Olson). The Palmer meets the claim limitations as described above except for the specific needle plane angles.

Regarding claims 5-6, 18 and 55, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Palmer with the needle plane angles as claimed in order to optimize the insertion into the skin, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

***Response to Arguments***

Applicant's arguments, see remarks, filed 11/26/2008, with respect to the rejection(s) of claim(s) 1-6, 8-13, 15-18, 20-25 and 53-56 under Trautman et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, a new ground(s) of rejection is made in view of Palmer (see above).

***Suggested Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

The Examiner suggests further clarification of the structural connection (12, 14, 22, 20) aspects of the abutment member and displacement mechanism as shown in Applicant's Figures 2A, 3A, 4A.



***Conclusion***

Applicant's amendment changing the claim scope necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 2/17/2009

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763